UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA

DANIEL BRODY, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. MYLAN N.V., HEATHER BRESCH, KENNETH S. PARK and RAJIV MALIK, Defendants.	Civil Action No. 2:19-cv-1620 **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT
FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Plaintiff Daniel Brody alleges the following based upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters. Plaintiff's information and belief is based on the investigation of his undersigned Counsel, which included, among other things, review and analysis of (i) public filings with the U.S. Securities and Exchange Commission ("SEC") of Mylan N.V. ("Mylan" or the "Company"); (ii) Mylan's other public statements, including press releases; (iii) reports of securities and financial analysts, news articles, and other commentary and analysis concerning Mylan and the industry in which it operates; and (iv) review of pertinent U.S. Food and Drug Administration ("FDA") documents. Counsel's investigation into the matters alleged herein is continuing, and many relevant facts are known only to, or are exclusively within, the custody or control of the Defendants. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federa1 securities class action on behalf of all investors who purchased or otherwise acquired Mylan securities between May 9, 2018, and May 6, 2019, inclusive (the "Class Period"), seeking remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

JURISDICTION AND VENUE

2. The federal law claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b) and § 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

3. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, § 27 of the Exchange Act, 15 U.S.C. §78aa. In connection with the acts, conduct and other wrongs alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the U.S. mail, interstate telephone communications and the facilities of the national securities exchange. Mylan trades in an efficient market on the Nasdaq Global Select Market ("Nasdaq" or "NasdaqGS").

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and § 27 of the Exchange Act because many of the false and misleading statements were made in or issued from this District. Defendants conduct business and maintain offices in this Judicial District, and Mylan is headquartered in this Judicial District, with its principal facilities and global headquarters located at 1000 Mylan Blvd, Canonsburg, PA 15317.

THE PARTIES

I. PLAINTIFFS

5. Plaintiff Daniel Brody, as set forth in the attached certification, incorporated by reference herein, purchased Mylan securities during the Class Period at artificially inflated prices, and has been damaged thereby.

II. DEFENDANTS

A. Mylan N.V.

6. Mylan is a Dutch company with its global headquarters located in Pennsylvania, United States. Mylan began in 1961 as a privately-owned distributor for pharmacies and doctors. In 1965, Mylan relocated to Pennsylvania and in 1973, Mylan became publicly traded. In 2015, Mylan acquired Abbott Laboratories' non-U.S. market specialties and branded generics business and became a public limited liability company in the Netherlands. The Company's common stock trades on the Nasdaq under the symbol "MYL." Mylan purports to identify itself as one of the nation's largest manufacturers of generic drugs with the goal to increase access to medicine through the power of competition and innovation. Mylan owns 16 manufacturing, distribution and administrative facilities in the U.S. and Puerto Rico, including a campus in Morgantown, West Virginia, which Mylan describes as to include "an R&D center of excellence and manufacturing plant."

B. The Individual Defendants

7. Defendant Heather Bresch ("Bresch") was the Company's Chief Executive Officer ("CEO") at all relevant times. Prior to becoming CEO in 2012, Bresch served as the company's President, where she was responsible for its day-to-day operations.

8. Defendant Kenneth S. Park ("Park") was the Company's Chief Financial Officer ("CFO") at all relevant times. Parks is responsible for all of Mylan's global finance functions, including accounting and control, financial planning and analysis, investor relations, treasury and tax.

9. Defendant Rajiv Malik ("Malik") was the Company's President, Executive Director at all relevant times. Malik is responsible for the day-to-day operations of the company, which includes Commercial, Scientific Affairs, Manufacturing, Supply Chain and Quality.

10. Defendants in paragraphs ¶7-9 are collectively referred to herein as the "Individual Defendants."

11. Each of the Individual Defendants:

i. directly participated in the management of the Company;

ii. was directly involved in the day-to-day operations of the Company at the highest levels;

iii. was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

iv. was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

v. was aware of or deliberately recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

vi. approved or ratified these statements in violation of the federal securities laws.

12. Because of the Individual Defendants' positions within the Company, they had access to undisclosed information about Mylan's business, operations, operational trends, financial statements, markets and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations and performance), conversations and connections with other corporate officers and employees, attendance at management and Board meetings and committees thereof and via reports and other information provided to them in connection therewith.

13. As officers of a publicly held company whose securities were, and are, registered with the SEC pursuant to the federal securities laws of the United States, the Individual Defendants each had a duty to disseminate prompt, accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, markets, management, earnings and present and future business prospects. The Individual Defendants also each had a duty to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

14. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Mylan's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, i.e., the market. Each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

15. Each of the Individual Defendants is liable as a participant in a fraudulent scheme

and course of business that operated as a fraud or deceit on purchasers of Mylan securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding Mylan's business, operations, management and the intrinsic value of its securities and (ii) caused Plaintiff and other shareholders to purchase Mylan securities at artificially inflated prices.

SUBSTANTIVE ALLEGATIONS

I. BACKGROUND

16. Mylan was founded in 1961 by Milan Puskar as a distributor and reseller of manufactured products for pharmacies and doctors. In 1965, the Company relocated to Morgantown, West Virginia to begin manufacturing vitamins and F.D.A. approved drugs such as Penicillin and Tetracycline. Nowadays, Mylan identifies itself as one of the nation's largest manufacturers of generic drugs with the goal to increase access to medicine through the power of competition and innovation.

17. Mylan offers more than 7,500 products, including prescription brand-name drugs, unbranded and branded prescription generic drugs and over-the-counter ("OTC") products and active pharmaceutical ingredients ("APIs"). Mylan operates in 3 segments: (i) North American; (ii) Europe; and (iii) Rest of World. The North American segment includes Mylan's operations in the U.S. and Canada; the Europe segment comprises operations in 35 countries including France, Italy, Germany, the U.K. and Spain; and the Rest of World segment includes 120 countries out of the other segments' zones. For the fiscal year ended December 31, 2017, the North American segment represented 42% of Mylan's net sales, while Europe represented 34% and the Rest of World 24%.

18. In the North American segment, Mylan's operations benefit extensively from the business it conducts in the U.S. with the sales of branded prescriptions such as EpiPen Auto-

Injector, Perforomist Inhalation Solution and Dymista and OTC products such as Cold-EEZE, MidNite, Levothyroxine and Vivarin.

19. Mylan owns 16 manufacturing, distribution and administrative facilities in the U.S. and Puerto Rico but identifies two principal Mylan facilities in its SEC filings: (i) the group's global headquarters in Canonsburg, Pennsylvania and (ii) Mylan's campus in Morgantown, West Virginia, which includes a manufacturing plant and a research and development ("R&D") center.

20. In 1965, Mylan relocated to Morgantown, West Virginia, to manufacture vitamins and FDA approved drugs. By 1999, Mylan owned three buildings in Morgantown totaling 473,000 square feet and reported, that year, the construction of a 65,000 square feet sales and administration facility and another 11,000 square feet production area in Morgantown.

21. Historically but also recently, the Morgantown facilities played an essential role for Mylan. The campus became one of Mylan's two "global R&D center[s] of excellence". In April 2018, various news outlets reported that Mylan was one of the largest employers in West Virginia with approximately 3,000 people working at its Morgantown facilities.

II. MATERIALLY FALSE AND MISLEADING STATEMENTS

22. The Class Period begins on May 9, 2018, when, before the market opened, Mylan issued a press release, also attached as exhibit 99.1 to the Form 8-K filed with the SEC, announcing the Company's financial and operating results for the first fiscal quarter ended March 31, 2018 ("Q1 2018 Press Release"). Therein, Mylan made material misrepresentations, including in pertinent part:

> Mylan CEO Heather Bresch commented: "Mylan's first quarter demonstrates continued execution on our long-term plan. Our diversity and durability are what allow us to absorb evolving industry dynamics and natural market volatility, while at the same time accelerate our mission of providing access to high quality medicine. ***Further demonstrating our commitment to access, I am pleased to share our newly released 2017 Global Social Responsibility Progress Report available at mylan.com***"

> President Rajiv Malik commented: "We continue to benefit from our diversified and durable global platform, with solid revenue performance from both our Europe and Rest of World segments. ***We also continue to execute on our key pipeline programs, as outlined during our recent Investor Day, while maintaining our confidence in our ability to bring these important products to market.*** From an operational standpoint, we are continuing to execute on our integration activities to further optimize our cost structure, at the same time we are investing across our business in areas such as sales and marketing of several global key products. These actions helped to support our performance during the quarter, and we expect to continue this execution throughout 2018."
>
> Mylan CFO Ken Parks added, "During the first quarter, we delivered adjusted EPS growth of 3%, in line with our expectations. In addition, we delivered strong adjusted free cash flow of $664 million, an increase of 39 percent over the prior year, driven by improved working capital velocity. This strength continues to demonstrate our stable and durable cash flow profile and supports our financial flexibility to execute on our business strategies and reduce debt levels, while maintaining our commitment to an investment grade credit rating. For the full year 2018, we are reaffirming our guidance and business outlook, including our total revenue range of $11.75 billion to $13.25 billion, adjusted EPS guidance range of $5.20 to $5.60 and adjusted free cash flow range of $2.1 billion to $2.5 billion."

23. The aforementioned Global Social Responsibility Progress Report (the "GSRPR") was released as part of Mylan's adherence to the United Nations (U.N.) Global Compact, a pact to take actions in support of U.N. aims and issues. Therein, Mylan issued the following statement:

> **Maintaining Quality Within our Supply Chain**
>
> Maintaining access to high quality raw materials and delivering finished goods in a timely manner is crucial to Mylan's ability to provide patients with access to the medicines they need. ***Mylan's global supply chain has been strategically designed to ensure that the right products reach the right customers (and ultimately patients) at the right time***. Many of our facilities are located in close proximity to the markets we serve, as shown below, and about 75% of the product volume we sell is produced through internally controlled manufacturing. ***To manage this network responsibly across many markets and engage with health authorities around the globe, we have a robust set of quality systems and controls in place.*** We also engage our suppliers and partners to address the full range of quality-related considerations involved in developing and manufacturing drugs, and we have quality agreements with our suppliers. ***In addition, we seek full compliance with all applicable laws, such as those focused on labor, the environment and anti-corruption for both our internal and external network of suppliers. We also make investments as appropriate to keep employees safe, the***

environment clean and quality high.

Emphasis added.

24. During a conference call discussing the Company's financial and operating results for the first fiscal quarter ended March 31, 2018 ("Q1 2018 Conf. Call"), Mylan's President Malik was asked about "product discontinuations" at its Morgantown facility. Here, he assured investors about the Morgantown's production capacity, stating, in relevant part:

> "***And regarding some product discontinuation, look, our Morgantown facility is perhaps one of the largest or solid facility with the capacity to do about 18 billion to 20 billion doses***.
>
> In the evolving FDA standards, especially around the cross contamination, we find it hard to keep pace with making hundreds of molecules. We make more than – over 200 molecules in the facility. ***And we have taken our time now to simplify the operations and make it less complex and rationalize some of the portfolio***. ***We have been very prudent. We have taken patient considerations in mind. We have kept our key customers and their needs in the mind***."

Emphasis added.

25. The same day, Mylan filed a Form 10-Q with the SEC announcing the Company's financial and operating results for the first fiscal quarter ended March 31, 2018 ("Q1 2018 10-Q"), which was signed and certified under the Sarbanes Oxley Act of 2002 by the Individual Defendants. Therein, Defendants asserted that: (1) the Company's disclosure controls and procedures were effective; (2) that there had been no material change in the Company's internal control over financial reporting that occurred during the first quarter of 2018 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting; and (3) there have been no material changes in the Company's risk factors from those disclosed in Mylan's Annual Report on Form 10-K for the year ended December 31, 2017, as amended.

26. On June 28, 2018, Mylan issued a press release, also attached as exhibit 99.1 to the

Form 8-K filed with the SEC announcing that the FDA recently completed an inspection at Mylan's plant in Morgantown and made observations through a Form 483 ("June 2018 Press Release"). The press release stated in pertinent part:

> Mylan Statement: Morgantown Operations
>
> Mylan is committed to maintaining the highest quality manufacturing standards at its facilities around the world. In support of this commitment, Mylan's plants are regularly inspected by health authorities to ensure compliance for the various markets we serve. The U.S. Food and Drug Administration (FDA) recently completed an inspection at Mylan's plant in Morgantown and made observations through a Form 483. The company has submitted a comprehensive response to the Agency and committed to a robust improvement plan. ***We remain confident in the quality, safety and efficacy of our drug products, including those in distribution, and we continue to manufacture and ship product from the site***. Mylan will continue to maintain a close dialogue with the Agency and is fully committed to working with FDA to address its observations.
>
> Emphasis added.

27. The statements in paragraphs ¶22-26 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations, and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) Mylan's Morgantown facility was in significant violation of the FDA's Current Good Manufacturing Practice ("CGMP") regulations; (2) Mylan would need to engage in a massive restructuring and remediation program; (3) Mylan's North American Segment would be substantially impacted by said program, which would in turn materially impact Mylan's financial health; (3) Mylan lacked effective internal control over financial reporting; and (4) as a result of the foregoing, the Company's financial statements were materially false and misleading at all relevant times.

III. THE TRUTH BEGINS TO EMERGE

28. On August 8, 2018, Mylan issued a press release, also attached as exhibit 99.1 to

the Form 8-K filed with the SEC, announcing the Company's financial and operating results for the second fiscal quarter and six months ended June 30, 2018 ("Q2 2018 Press Release"). Therein, Mylan disclosed the restructuring program at its Morgantown facility. In relevant part:

> Mylan is committed to maintaining the highest quality manufacturing standards at its facilities around the world. In support of this commitment, Mylan's plants are regularly inspected by health authorities to ensure compliance for the various markets we serve. The U.S. Food and Drug Administration ("FDA") recently completed an inspection at Mylan's plant in Morgantown, West Virginia and made observations through a Form 483. The Company has submitted a comprehensive response to the FDA and committed to a robust improvement plan. In addition, the Company has recognized that the industry dynamics and regulatory expectations have continued to evolve. ***Based upon these factors and the Company's commitment, during the second quarter of 2018, the Company commenced a restructuring and remediation program at the Morgantown manufacturing facility. The program, which includes a reduction of the workforce and the discontinuation of a number of products, is aimed at reducing complexity at the facility.*** These actions have had a significantly negative impact on production levels, product supply and operations. Also, the Company has incurred significant expenses for incremental manufacturing variances, site remediation and restructuring charges. The Company expects that remediation activities, lower production levels, the negative impact on operations and related expenses to continue through the end of 2018.

29. During a conference call to discuss the Company's financial and operating results for the second fiscal quarter and six months ended June 30, 2018 ("Q2 2018 Conf. Call"), Mylan's President Malik confirmed the restructuring and remediation program, stating in relevant part:

> I'll now provide the latest update on our sites in Morgantown and Nashik. Mylan has always been and remains committed to maintaining the highest quality manufacturing standards at its facilities around the world. At the end of the June, we released a statement confirming that the FDA had completed a recent inspection in Morgantown and made observations in a Form 483. We have submitted a comprehensive response to FDA and are committed to a robust remediation and improvement plan.
>
> As a result of FDA's evolving regulatory expectations, our commitment to maintain high quality standards has left changing industry dynamics. ***We have undertaken a restructuring and remediation program in Morgantown during the second quarter of 2018. The program, which includes a discontinuation of a number of products, is aimed at reducing complexity at the facility***.

> These actions have temporarily had a negative impact on production levels, product supplies, and operations. However, long term these actions will only further strengthen our Morgantown site.
>
> Emphasis added.

30. On this news, the price of the Company's common stock declined $2.62 from a close on August 8, 2018 of $39.23 per share of Mylan common stock, to a close on August 9, 2018 of $36.61 per share of Mylan common stock, ***a drop of approximately 6.68 percent.***

IV. ADDITIONAL MISSTATEMENTS

31. On November 5, 2018, Mylan issued a press release, also attached as exhibit 99.1 to the Form 8-K filed with the SEC, announcing the Company's financial and operating results for the third fiscal quarter and nine months ended September 30, 2018 ("Q3 2018 Press Release"). Therein, Mylan stated in relevant part:

> Mylan CEO Heather Bresch said: "Mylan's third quarter performance was in line with our expectations and we delivered solid year-over-year growth. ***Our confidence in the company's bright future extends well beyond any single factor or particular quarter, including the current, short-term macro market turbulence our industry is experiencing.*** Year-to-date, we have launched nearly 475 new products across our segments, including a record number of complex generics and biosimilars for Mylan. These medicines represent many different therapeutic categories, channels and dosage forms.
>
> We remain committed to our full-year 2018 guidance, and this confirmation is not dependent on any single product approval or launch. As we look ahead, we're very optimistic about our long-term growth prospects as we have secured almost all regulatory approvals necessary for our key 2019 product drivers around the world."
>
> Mylan President Rajiv Malik continued: "This record year of scientific accomplishments represents a significant milestone in the company's nearly 60-year history. ***Our recent successes demonstrate the strength of our scientific platform and our ability to manage and execute on new products, including complex generics and biologics. These milestones are the culmination of years-long scientific investments and reinforce our dedication to enhance access to patients. The Mylan teams managing the science and working closely with our partners have consistently delivered remarkable results, and we look forward to continuing this momentum as we close out 2018***."

> Mylan CFO Ken Parks added: "Mylan continues to generate strong cash flow with more than $2.0 billion of adjusted free cash flow for the first nine months of 2018, up 6% from the prior year and a healthy 119% of adjusted net earnings of $1.7 billion. We remain confident in our full year adjusted free cash flow outlook. As anticipated, our capital deployment priority is focused on deleveraging in the second half of 2018, and we expect this to continue into 2019. We intend to repay at least $1.2 billion of debt maturing through year end 2019 and remain fully committed to maintaining our investment grade credit rating."

32. During a conference call to discuss the Company's financial and operating results for the third fiscal quarter and nine months ended September 30, 2018 ("Q3 2018 Conf. Call"), Mylan's President Malik stated in relevant part:

> "Let me start by celebrating the broad contribution impact of our Morgantown facility, restructuring and remediation which began in the second quarter of this year on our North American business, as this may have been misunderstood by the investment community.
>
> * * *
>
> As we work to reduce the complexity of this facility, we have proactively discontinued a number of products, while also transferring some to other sites. These actions have led to a temporary disruption in supply of certain products for our customers and reduced volume in North America generic sales. However, the value related to the rationalize product is not proportionate to the reduced volumes of those commoditized products.
>
> While we are executing on our commitment to FDA, the plant continues to supply products for the U.S. market. Our remediation and restructuring activities will continue in the near-term. We understand that this current and temporary situation post a burden on our customers and appreciate their ongoing confidence in Mylan, based on our outstanding historical track record.
>
> As one of world's largest pharmaceutical market, the U.S. remains a key market for Mylan. We will continue to focus on providing a broad range of products, including industry-leading new launches and maintaining a meaningful market share across a diversified portfolio. ***No matter, where our products are produced in our network, our goal is to ensure the highest quality and service levels to our customer and optimal volume value mix***.
>
> As Heather mentioned, over the past 12 months, we have had a record-breaking year of scientific accomplishments, representing a significant milestone in the company's nearly 60-year history and validating our strength in managing and executing on complex product approvals. This is a culmination of year's long

> scientific investments and endeavors to bring complex generics and biosimilars to the market."

Emphasis added.

33. The statements in paragraphs ¶31-32 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations, and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) Mylan's Morgantown facility was in significant violation of the FDA's Current Good Manufacturing Practice ("CGMP") regulations; (2) Mylan was engaging in a massive restructuring and remediation program; (3) Mylan's North American Segment was substantially impacted by said program, which in turn materially impacted Mylan's financial health; (3) Mylan lacked effective internal control over financial reporting; and (4) as a result of the foregoing, the Company's financial statements were materially false and misleading at all relevant times.

V. THE TRUTH CONTINUES TO EMERGE

34. Four days later, on November 9, 2018, the FDA issued a Warning Letter to Mylan (the "2018 Warning Letter"), stating in relevant part:

> The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Mylan Pharmaceuticals, Inc. at 781Chestnut Ridge, Morgantown, West Virginia, from March 19, 2018, to April 12, 2018.
>
> This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.
>
> Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).
>
> We reviewed your May 3, 2018, response in detail and acknowledge receipt of

your subsequent correspondence.

During our inspection, our investigators observed specific violations including, but not limited to, the following.

1. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a)).

* * *

2. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

* * *

3. Your firm failed to follow written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess, and to record and justify any deviations from them (21 CFR 211.100(b)).

* * *

Quality Unit Authority

Your inspectional history and significant findings in this letter indicate that your quality unit is not fully exercising its authority and/or responsibilities. For example, your quality unit failed to ensure that cleaning operations are adequate to prevent crosscontamination; manufacturing changes are appropriately evaluated; manufacturing processes are robust and capable of consistently delivering quality product; and investigations are effective. Your firm must provide the quality unit with the appropriate authority, sufficient resources, and staff to carry out its responsibilities and consistently ensure drug quality.

Quality Systems Guidance

Your firm's quality systems are inadequate. For guidance on establishing and following CGMP compliant quality systems to establish and maintain an ongoing state of control, see FDA's guidances[.]

* * *

> Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance. You should immediately and comprehensively assess your company's global manufacturing operations to ensure that systems and processes, and ultimately, the products you manufacture, consistently conform to FDA requirements.
>
> **CGMP consultant recommended**
>
> Because you failed to correct repeat violations, we strongly recommend engaging an independent third party qualified as set forth in 21 CFR 211.34, to assist your firm in meeting CGMP requirements. Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.

35. On November 20, 2018, during morning market hours, Scott Gottlieb, the FDA's Commissioner, issued the following tweet about the 2018 Warning Letter:

> An important aspect of ensuring drug safety is adherence to current good manufacturing practices. Recently #FDA issued a warning letter to Mylan Pharmaceuticals for CGMP violations. We expect the firm to work to resolve the issues identified by the #FDA

36. On February 26, 2019, after the market closed, Mylan issued a press release, also attached as exhibit 99.1 to the Form 8-K filed with the SEC, announcing the Company's financial and operating results for the fourth fiscal quarter and fiscal year ended December 31, 2018 ("FY 2019 Press Release"). Therein, the Mylan stated in relevant part:

> **Fourth Quarter 2018 Financial Highlights**
>
> • Total revenues of $3.08 billion, down 5% compared to the prior year period
>
> ◦ Rest of World segment net sales of $851.4 million, up 4%, up 11% on a constant currency basis
>
> ◦ Europe segment net sales of $1.09 billion, up 1%, up 5% on a constant currency basis
>
> ◦ ***North America segment net sales of $1.10 billion, down 16%, on an actual and constant currency basis, primarily due to lower volumes on existing products, which was primarily driven by actions associated with the restructuring and remediation activities at the Morgantown plant*** and the timing of purchases of our products by customers, as well as the impact of the implementation of new accounting

standards

• U.S. GAAP diluted earnings per ordinary share ("U.S. GAAP EPS") of $0.10, down 78% over the prior year period

• Adjusted diluted earnings per ordinary share ("adjusted EPS") of $1.30, down 9% over the prior year period

Full Year 2018 Financial Highlights

• Total revenues of $11.43 billion, down 4% compared to the prior year
◦ Rest of World segment net sales of $3.02 billion, up 7%, up 10% on a constant currency basis
◦ Europe segment net sales of $4.16 billion, up 5%, up 1% on a constant currency basis
◦ ***North America segment net sales of $4.10 billion, down 18%, on an actual and constant currency basis, primarily due to lower volumes on existing products***, including the EpiPen® Auto-Injector sales, which was primarily driven by the divestiture of certain contract manufacturing assets, the loss of exclusivity of certain products, ***actions associated with the restructuring and remediation activities at the Morgantown plant and the timing of purchases of our products by customers***, as well as the impact of the implementation of new accounting standards

• U.S. GAAP EPS of $0.68, down 47% compared to the prior year

• Adjusted EPS of $4.58, up slightly when compared to the prior year

• U.S. GAAP net cash provided by operating activities of $2.34 billion, up 13% compared to $2.06 billion in the prior year period

• Adjusted free cash flow of $2.71 billion, up 3% compared to $2.63 billion in the prior year period.

37. During a conference call to discuss the Company's financial and operating results for the fourth fiscal quarter and fiscal year ended December 31, 2018 ("FY 2018 Conf. Call"), Mylan's President Malik stated in relevant part:

> ***Our business in North America had net sales of $4.1 billion, a decrease of 18% from the prior year***. This was primarily impacted due to the lower than anticipated update of generic Copaxone and delayed approval of generic Advair. ***As part of our Morgantown remediation and restructuring activity and accelerated commoditization of oral solids, we discontinued almost 250 SKUs of highly commoditized oral solid products***. North America benefited from some

> exciting launches of Fulphila, DAPTOMYCIN and exclusive 180 days of Tadalafil and full year impact of generic Copaxone.
>
> I will address Morgantown plant. After the April 2018 inspection and receipt of a 483 form the company took a comprehensive restructuring and remediation of the Morgantown plant to address the issues that had been identified.
>
> Notwithstanding these efforts, the company received a warning letter related to the previously disclosed observations in the fourth quarter. The issues raised in the warming letter are being comprehensively addressed. The Morgantown plant continues to supply products for the U.S. market, while we execute on and assess the restructuring and remediation activities.
>
> ***No significant new product revenue is forecasted from the Morgantown plant in 2019. Also we look at our business in North America, only five of our top 50 gross margin generating products are currently manufactured in Morgantown***.
>
> Emphasis added.

38. On this news, the price of the Company's common stock declined $4.61 from a close on February 26, 2019, of $30.62 per share of Mylan common stock, to a close on February 27, 2019 of $26.01 per share of Mylan common stock, ***a drop of approximately 15.06 percent.***

39. Following the news, an analyst from MorningStar lowered its Fair Value Estimate, an indication of the long-term intrinsic value of the stock because Mylan was experience higher costs stemming from the 2018 Warning Letter.

40. On May 7, 2019, before the market opened, Mylan issued a press release, also attached as exhibit 99.1 to the Form 8-K filed with the SEC, announcing the Company's financial and operating results for the first fiscal quarter ended March 31, 2019 ("Q1 2019 Press Release"). Therein, the Mylan stated in relevant part:

> **First Quarter 2019 Financial Highlights**
>
> • U.S. GAAP diluted loss per ordinary share ("U.S. GAAP EPS") of $(0.05) as compared to earnings of $0.17 per ordinary share in the prior year period.
>
> • Total revenues of $2.50 billion, down 7% compared to the prior year

period and adjusted diluted earnings per ordinary share ("adjusted EPS") of $0.82, down 15% over the prior year period.

• Revenue Highlights:
◦ Rest of World segment net sales of $642.4 million, up 3%, up 11% on a constant currency basis.
◦ Europe segment net sales of $895.3 million, down 14%, down 6% on a constant currency basis.
◦ ***North America segment net sales of $922.9 million, down 6% on an actual and constant currency basis, primarily driven by changes in the competitive environment and the impact of the Morgantown plant remediation activities.***

• U.S. GAAP net cash used in operating activities for the three months ended March 31, 2019 of $(39.7) million, compared to U.S. GAAP net cash provided by operating activities of $621.8 million in the prior year period and adjusted free cash flow for the three months ended March 31, 2019 of $27.1 million, compared to $663.6 million in the prior year period, driven primarily by an increased investment in working capital.

Emphasis added.

41. On this news, the price of the Company's common stock declined $6.73 from a close on May 6, 2019, of $28.26 per share of Mylan common stock, to a close on May 7, 2019 of $21.53 per share of Mylan common stock, ***a drop of approximately 23.81 percent.***

42. Following the news, RBC Capital Markets cut its price target from $45 to $26 and released a research report entitled "Investor frustration justified and change is needed" stating that "management challenges forecasting the business, delays in responding to industry change and governance frustrations" were the reasons for the sell-off.

ADDITIONAL SCIENTER ALLEGATIONS

43. As alleged herein, each of the Individual Defendants acted with scienter in that they knew or recklessly disregarded that the public statements and documents issued and disseminated in the name of the Company were materially false and misleading, knew or acted with deliberate recklessness in disregarding that such statements and documents would be issued and disseminated

to the investing public, and knowingly and substantially participated and/or acquiesced in the issuance or dissemination of such statements and documents as primary violators of the federal securities laws.

44. The Individual Defendants had the opportunity to commit and participate in the wrongful conduct complained of herein. Each was a senior executive officer and/or director of Mylan and, thus, controlled the information disseminated to the investing public in the Company's press releases, investor conference calls and SEC filings. As a result, each could falsify the information that reached the public about the Company's business and performance.

45. Throughout the Class Period, each of the Individual Defendants acted intentionally or recklessly and participated in and orchestrated the fraudulent schemes herein to inflate the Company's stock price and profit from insider sales of large blocks of their personal holdings of Mylan's stock. The Individual Defendants' scienter may be imputed to Mylan as the Individual Defendants were among the Company's most senior management and were acting within the scope of their employment.

LOSS CAUSATION AND ECONOMIC LOSS

46. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the Company's stock price and operated as a fraud or deceit on acquirers of the Company's common stock. As detailed above, when the truth about Mylan's misconduct and its lack of operational and financial controls was revealed, the value of the Company's common stock declined precipitously as the prior artificial inflation no longer propped up its stock price. The decline in Mylan's common stock price was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the common stock price decline negates any inference

that the loss suffered by Plaintiff and other members of the Class was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the Defendants' fraudulent conduct. The economic loss, i.e., damages, suffered by Plaintiff and other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the Company's stock price and the subsequent significant decline in the value of the Company's share, price when Defendants' prior misrepresentations and other fraudulent conduct was revealed.

47. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the Plaintiff and other Class members. Those statements were materially false and misleading through their failure to disclose a true and accurate picture of Mylan's business, operations and financial condition, as alleged herein. Throughout the Class Period, Defendants publicly issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing Mylan's common stock to be artificially inflated. Plaintiff and other Class members purchased Mylan's common stock at those artificially inflated prices, causing them to suffer the damages complained of herein

CLASS ACTION ALLEGATIONS

48. Plaintiff brings this action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a class of all persons or entities that purchased or otherwise acquired Mylan publicly traded securities between May 9, 2018 and May 6, 2019, inclusive, seeking to pursue remedies under the Exchange Act (the "Class"). Excluded from the Class are Mylan and its subsidiaries and affiliates, and their respective officers and directors at all relevant times, and any of their immediate families, legal representatives, heirs, successors, or assigns, and any entity in which any Defendant has or had a controlling interest.

49. Because Mylan securities were actively traded on the NasdaqGS, the members of the Class are so numerous that joinder of all Class members is impracticable. While the exact number of Class members is unknown at this time and can only be ascertained through discovery, Plaintiff believes that there are hundreds or thousands of Class members. As of July 23, 2019, there were 515,869,921 shares of Mylan common stock outstanding. Members of the Class may be identified from records maintained by Mylan or its transfer agent and may be notified of the pendency of this action by mail, using forms of notice customarily used in securities class actions.

50. Plaintiff's claims are typical of those of the members of the Class, as all Class members have been similarly affected by Defendants' wrongful conduct as alleged herein. Moreover, Plaintiff will fairly and adequately protect the interests of the Class and have retained counsel competent and experienced in class action and securities litigation.

51. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. These common questions include:

a. Whether Defendants violated the federal securities laws as alleged herein;

b. Whether Defendants' statements to the investing public during the Class Period misrepresented material facts about Mylan's business and operations;

c. Whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether the Individual Defendants caused Mylan to issue false and misleading SEC filings and public statements during the Class Period;

e. Whether the Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;

f. Whether the prices of Mylan securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

g. Whether the members of the Class have sustained damages and, if so, the proper measure of damages.

52. A class action is superior to all other available methods for the fair and efficient adjudication of this matter as joinder of all Class members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

NO STATUTORY SAFE HARBOR

53. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Amended Class Action Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Mylan who knew that the statement was false when made.

APPLICABILITY OF FRAUD ON THE MARKET DOCTRINE

54. The market for Mylan securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Mylan securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired the Company's stock relying upon the integrity of the market price of Mylan and market information relating to the Company, and have been damaged thereby.

55. During the Class Period, the artificial inflation of Mylan securities was caused by the material misrepresentations and/or omissions particularized in this Amended Class Action Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, the Defendants named in this Action made or caused to be made a series of materially false and/or misleading statements about Mylan's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Mylan and its business, operations, and prospects, thus causing the price of the Company's stock to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. The Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's stock at such artificially inflated prices, and each of them has been damaged as a result.

56. At all relevant times, the market for Mylan securities was an efficient market for the following reasons:

a. Mylan common stock met the requirements for listing, and was listed and actively

traded on the NasdaqGS, a highly efficient and automated market;

b. As a regulated issuer, Mylan filed periodic public reports with the SEC and the NasdaqGS;

c. Mylan communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

d. During the Class Period, on average, over tens of millions of Mylan shares were traded on a weekly basis. On news days, the Company's trading volume increased into the hundreds of millions, reflecting an active trading market for Mylan common stock and investors' expectations being impounded into the stock price; and

e. The proportion of statistically significant stock price movement days for Mylan common stock on news days is significantly over the proportion of non-news days and, thus, Mylan common stock is more likely to have a statistically significant return on a day with news than no-news, consistent with an informationally efficient market.

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against Mylan and the Individual Defendants

57. Plaintiff realleges each allegation as if fully set forth herein.

58. This claim is brought under §10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, against Mylan, Longhi, Burritt, and Lesnak (the "Count I Defendants").

59. The Count I Defendants: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted material facts necessary to make the

statements made not misleading; and (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon Plaintiff and the Class, in violation of §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

60. The Count I Defendants individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal non-public, adverse material information about the Company's outlook and condition, as reflected in the misrepresentations and omissions set forth above.

61. The Count I Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

62. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them, or other personnel of the Company to members of

the investing public, including Plaintiff and the Class.

63. As a result of the foregoing, the market price of Mylan securities was artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of Mylan securities during the Class Period in purchasing Mylan securities at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

64. Had Plaintiff and the other members of the Class been aware that the market price of Mylan securities had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information which the Company's and the Individual Defendants did not disclose, they would not have purchased Mylan securities at the artificially inflated prices that they did, or at all.

65. As a result of the wrongful conduct alleged herein, Plaintiff and the other members of the Class have suffered damages in an amount to be established at trial.

66. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of Mylan securities during the Class Period.

COUNT II

For Violations of Section 20(a) of the Exchange Act Against Mylan and the Individual Defendants

67. Plaintiff realleges each allegation as if fully set forth herein.

68. This claim is brought under §20(a) of the Exchange Act, 15 U.S.C. § 78t, against Mylan, Longhi, Burritt, and Lesnak (the "Count II Defendants").

69. Each of the Count II Defendants, by reason of their status as senior executive officers and/or directors of Mylan, directly or indirectly, controlled the conduct of the Company's business and its representations to Plaintiff and the Class, within the meaning of §20(a) of the Exchange Act. The Count II Defendants directly or indirectly controlled the content of the Company's SEC statements and press releases related to Plaintiff and the Class' investments in Mylan securities within the meaning of §20(a) of the Exchange Act. Therefore, the Count II Defendants are jointly and severally liable for the Company's fraud, as alleged herein.

70. The Count II Defendants controlled and had the authority to control the content of the Company's SEC statements and press releases. Because of their close involvement in the everyday activities of the Company, and because of their wide-ranging supervisory authority, the Count II Defendants reviewed or had the opportunity to review these documents prior to their issuance, or could have prevented their issuance or caused them to be corrected.

71. The Count II Defendants knew or recklessly disregarded the fact that Mylan's representations were materially false and misleading and/or omitted material facts when made. In so doing, the Count II Defendants did not act in good faith.

72. By virtue of their high-level positions and their participation in and awareness of Mylan's operations and public statements, the Count II Defendants were able to and did influence and control Mylan's decision-making, including controlling the content and dissemination of the documents that Plaintiff and the Class contend contained materially false and misleading information and on which Plaintiff and the Class relied.

73. The Count II Defendants had the power to control or influence the statements made giving rise to the securities violations alleged herein, and as set forth more fully above.

74. As set forth herein, the Count II Defendants each violated §10(b) of the Exchange

Act and Rule 10b-5, thereunder, by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, the Count II Defendants are also liable pursuant to §20(a) of the Exchange Act.

75. As a direct and proximate result of the Count II Defendants' wrongful conduct, Plaintiff and the Class suffered damages in connection with their purchase of Mylan securities.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying the Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other relief as the Court may deem just and proper.

JURY DEMAND

In accordance with Fed. R. Civ. P. 38(b), Plaintiff demands a jury trial of all issues involved, now, or in the future, in this action.

Dated: December 16, 2019 Respectfully submitted,

PRIBANIC & PRIBANIC, LLC
Vincent A. Coppola
513 Court Place
Pittsburgh, PA 15219
Tel: (412) 281-8844
Fax: (412) 281-4740
Email: vcoppola@pribanic.com

/s/ Vincent A. Coppola

Liaison Counsel

LEVI & KORSINSKY, LLP (Trial Counsel)
Eduard Korsinsky
55 Broadway, 10th Floor
New York, NY 10006
Tel: (212) 363-7500
Fax: (212) 363-7171
Email:ek@zlk.com
(*Pro hac vice application forthcoming*)

Counsel for Plaintiff and Proposed Lead Counsel for the Class